March 27, 2015

ENGROSSED
SENATE BILL No. 358

DIGEST OF SB 358 (Updated March 26, 2015 10:01 am - DI 77)

Citations Affected: IC 25-26; IC 35-48; noncode.

Synopsis: Medications. Defines "medication therapy management" for the purposes of the regulation of pharmacies and pharmacists. Adds the provision of medication therapy management to the definition of "the practice of pharmacy". Includes advanced practice nurses and physician assistants in the definition of "direct supervision" for the purposes of consulting with a pharmacist on certain drug regimen protocols. Establishes the INSPECT oversight committee. Provides the committee's approval for the board to execute a contract with a vendor to administer the INSPECT program. Requires approval from the chairperson of the board of pharmacy to hire a director of the INSPECT program. Provides that if a dispenser's pharmacy is closed the day following a dispensing, the information required to be sent to the INSPECT program must be transmitted by the end of the next business day. Amends the definition of "medication assistance" in the administrative code for purposes of the rules concerning home health agencies.

Effective: July 1, 2015.

Grooms, Becker, Kruse

(HOUSE SPONSORS — DAVISSON, CLERE, STEMLER)

January 8, 2015, read first time and referred to Committee on Family & Children Services.
January 27, 2015, amended, reported favorably — Do Pass.
January 29, 2015, read second time, amended, ordered engrossed.
January 30, 2015, engrossed.
February 2, 2015, read third time, passed. Yeas 44, nays 0.

HOUSE ACTION

March 2, 2015, read first time and referred to Committee on Public Health.
March 26, 2015, amended, reported — Do Pass.

March 27, 2015

First Regular Session 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

ENGROSSED
SENATE BILL No. 358

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 25-26-13-2, AS AMENDED BY THE TECHNICAL CORRECTIONS BILL OF THE 2015 GENERAL ASSEMBLY, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 2. As used in this chapter:

"Administering" means the direct application of a drug to the body of a person by injection, inhalation, ingestion, or any other means.

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a

suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine,

contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Medication therapy management" means a distinct service or group of services that optimize therapeutic outcomes for individuals that are independent of, but may occur in conjunction with, the provision of a medication or medical device. The term

includes the following services:

(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management services within the broader health care services being provided to an individual.

(10) Providing other patient care services allowable by law.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience

as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section ~~18(a)(4)~~ **18.5** of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other

means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 2. IC 25-26-16-4.5, AS ADDED BY P.L.197-2011, SECTION 113, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 4.5. (a) This section does not apply to a pharmacist who is practicing in a hospital.

(b) As used in this section, "direct supervision" means that the supervising:

(1) physician;

(2) advanced practice nurse who meets the requirements of IC 25-23-1-19.5; or

(3) physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6;

is readily available to consult with the pharmacist while the protocol

services are being provided.

(c) This section applies to a pharmacist who:

(1) is employed by, or has entered into a contract with, a physician, a group of physicians, or an outpatient clinic; and

(2) is under the direct supervision of a ~~physician.~~ **person described in subsection (b)(1) through (b)(3).**

(d) The protocols developed under this chapter must:

(1) be developed by the physician described in subsection (c)(2) and the pharmacist; and

(2) at a minimum, require that:

(A) the medical records of the patient are available to both the patient's physician and the pharmacist; and

(B) the procedures performed by the pharmacist relate to a condition for which the patient has first seen the physician or another licensed practitioner.

SECTION 3. IC 35-48-7-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 2.5. As used in this chapter, "committee" refers to the INSPECT oversight committee established by section 17 of this chapter.**

SECTION 4. IC 35-48-7-8.1, AS AMENDED BY P.L.131-2014, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency

registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section must be transmitted as follows:

(A) Before July 1, 2015, not more than seven (7) days after the date on which a controlled substance is dispensed.

(B) Beginning July 1, 2015, and until December 31, 2015, not more than three (3) days after the date on which a controlled substance is dispensed.

(C) Beginning January 1, 2016, and thereafter, not more than twenty-four (24) hours after the date on which a controlled substance is dispensed. **However, if the dispenser's pharmacy is closed the day following the dispensing, the information must be transmitted by the end of the next business day.**

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) The board shall consider the recommendations of the committee concerning the INSPECT program.

~~(b)~~ **(c)** This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled

substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 5. IC 35-48-7-10.1, AS AMENDED BY P.L.84-2010, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 10.1. (a) The INSPECT program must do the following:

(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the board, including search capability for the following:

(A) A controlled substance recipient's name.

(B) A controlled substance recipient's or recipient representative's identification number.

(C) A controlled substance recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.

(F) The quantities of a controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(K) A controlled substance recipient's method of payment for the controlled substance dispensed.

(2) Provide the board with continuing twenty-four (24) hour a day online access to the data base.

(3) Secure the information collected and the data base maintained against access by unauthorized persons.

(b) The board may **not** execute a contract with a vendor designated by the board to perform any function associated with the administration of the INSPECT program, **unless the contract has been approved by the committee.**

(c) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.

(d) The board may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

SECTION 6. IC 35-48-7-12.1, AS AMENDED BY P.L.131-2014, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.

(2) Design for the creation of the data base required under section 10.1 of this chapter.

(3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.

(5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program:

(A) before initially prescribing a controlled substance to a patient; and

(B) periodically during the course of treatment that uses a controlled substance.

(b) The board may:

(1) set standards for education courses for individuals authorized to use the INSPECT program;

(2) identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program; and

(3) work with impaired practitioner associations to provide intervention and treatment.

(c) The executive director of the Indiana professional licensing agency may hire a person to serve as the director of the INSPECT program, with the approval of the chairperson of the board.

SECTION 7. IC 35-48-7-17 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 17. (a) The INSPECT oversight committee is established.**

(b) The committee consists of the following members:

(1) The president of the board or the president's designee, who shall serve as the chairperson of the committee.

(2) The commissioner of the state department of health or the commissioner's designee.

(3) The superintendent of the state police department or the superintendent's designee.

(4) The attorney general or the attorney general's designee.

(5) Two (2) lay members who are authorized users of the INSPECT program appointed by the president pro tempore of the senate, not more than one (1) of whom may be affiliated with the same political party.

(6) Two (2) lay members who are authorized users of the INSPECT program appointed by the speaker of the house of representatives, not more than one (1) of whom may be affiliated with the same political party.

(c) The committee shall provide recommendations to the board concerning the implementation of policies, standards, and rules that promote the effective operation of the program.

(d) The committee shall meet:

(1) at least once each calendar year; and

(2) at the call of the chairperson.

(e) Except as provided in subsection (f), the term of a member of the committee appointed under this section is four (4) years. The term of a member of the committee expires July 1, but a member may continue to serve on the committee until a successor is appointed.

(f) The initial terms for the members appointed under this section are as follows:

(1) One (1) member appointed under subsection (b)(5) has a term of four (4) years.

(2) One (1) member appointed under subsection (b)(6) has a term of three (3) years.

(3) One (1) member appointed under subsection (b)(5) has a term of two (2) years.

(4) One (1) member appointed under subsection (b)(6) has a term of one (1) year.

This subsection expires July 1, 2019.

SECTION 8. [EFFECTIVE JULY 1, 2015] **(a) Notwithstanding 410 IAC 17-9-20, for purposes of 410 IAC 17, the term "medication assistance" means the provision of assistance:**

(1) through providing reminders or cues to take medication, the opening of preset medication containers, and providing

assistance in the handling or ingesting of medications, including controlled substances, prescription drugs, eye drops, herbs, supplements, and over-the-counter medications; and

(2) to an individual who is unable to accomplish the task due to an impairment and who is:

(A) competent and has directed the services; or

(B) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(b) Before July 1, 2016, the state department of health shall adopt rules under IC 4-22-2 to amend 410 IAC 17-9-20 to adopt the definition of "medical assistance" as set forth in subsection (a).

(c) This SECTION expires on the earlier of the following:

(1) The date that rules are adopted under subsection (b).

(2) January 1, 2017.

COMMITTEE REPORT

Madam President: The Senate Committee on Family and Children Services, to which was referred Senate Bill No. 358, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Page 1, delete lines 1 through 16, begin a new paragraph and insert:

"SECTION 1. IC 25-26-13-2, AS AMENDED BY THE TECHNICAL CORRECTIONS BILL OF THE 2015 GENERAL ASSEMBLY, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 2. As used in this chapter:

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"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

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"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and

signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or device when it is administered to the patient; and the name of the prescriber.

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(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic

device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

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(1) attached to or logically associated with a record; and

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(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance

patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management services within the broader health care services being provided to an individual.

(10) Providing other patient care services allowable by law.

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"Practitioner" has the meaning set forth in IC 16-42-19-5.

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"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

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or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section ~~18(a)(4)~~ **18.5** of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 2. IC 25-26-16-4.5, AS ADDED BY P.L.197-2011, SECTION 113, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 4.5. (a) This section does not apply to a pharmacist who is practicing in a hospital.

(b) As used in this section, "direct supervision" means that the supervising:

(1) physician;

(2) advanced practice nurse who meets the requirements of IC 25-23-1-19.5; or

(3) physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6;

is readily available to consult with the pharmacist while the protocol services are being provided.

(c) This section applies to a pharmacist who:

(1) is employed by, or has entered into a contract with, a physician, a group of physicians, or an outpatient clinic; and

(2) is under the direct supervision of a physician.

(d) The protocols developed under this chapter must:

(1) be developed by the physician described in subsection (c)(2) and the pharmacist; and

(2) at a minimum, require that:

(A) the medical records of the patient are available to both the patient's physician and the pharmacist; and

(B) the procedures performed by the pharmacist relate to a condition for which the patient has first seen the physician or another licensed practitioner.".

Delete pages 2 through 8.

and when so amended that said bill do pass.

(Reference is to SB 358 as introduced.)

GROOMS, Chairperson

Committee Vote: Yeas 8, Nays 0.

SENATE MOTION

Madam President: I move that Senate Bill 358 be amended to read as follows:

Page 7, line 5, strike "physician." and insert "**person described in subsection (b)(1) through (b)(3).**".

(Reference is to SB 358 as printed January 28, 2015.)

GROOMS

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred Senate Bill 358, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Page 7, after line 15, begin a new paragraph and insert:

"SECTION 3. IC 35-48-7-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 2.5. As used in this chapter, "committee" refers to the INSPECT oversight committee established by section 17 of this chapter.**

SECTION 4. IC 35-48-7-8.1, AS AMENDED BY P.L.131-2014, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 8.1. (a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the board

under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the board.

(2) The information required to be transmitted under this section must be transmitted as follows:

(A) Before July 1, 2015, not more than seven (7) days after the date on which a controlled substance is dispensed.

(B) Beginning July 1, 2015, and until December 31, 2015, not more than three (3) days after the date on which a controlled substance is dispensed.

(C) Beginning January 1, 2016, and thereafter, not more than twenty-four (24) hours after the date on which a controlled substance is dispensed. **However, if the dispenser's pharmacy is closed the day following the dispensing, the information must be transmitted by the end of the next business day.**

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the board.

(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement

to prescriptions filled at a pharmacy with a Category II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) The board shall consider the recommendations of the committee concerning the INSPECT program.

~~(b)~~ **(c)** This subsection applies only to a retail pharmacy. A pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance may not dispense a controlled substance to a person who is not personally known to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance unless the person taking possession of the controlled substance provides documented proof of the person's identification to the pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance.

SECTION 5. IC 35-48-7-10.1, AS AMENDED BY P.L.84-2010, SECTION 98, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 10.1. (a) The INSPECT program must do the following:

(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the board, including search capability for the following:

(A) A controlled substance recipient's name.

(B) A controlled substance recipient's or recipient representative's identification number.

(C) A controlled substance recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.

(F) The quantities of a controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency

registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(K) A controlled substance recipient's method of payment for the controlled substance dispensed.

(2) Provide the board with continuing twenty-four (24) hour a day online access to the data base.

(3) Secure the information collected and the data base maintained against access by unauthorized persons.

(b) The board may **not** execute a contract with a vendor designated by the board to perform any function associated with the administration of the INSPECT program, **unless the contract has been approved by the committee.**

(c) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.

(d) The board may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

SECTION 6. IC 35-48-7-12.1, AS AMENDED BY P.L.131-2014, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 12.1. (a) The board shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.

(2) Design for the creation of the data base required under section 10.1 of this chapter.

(3) Requirements for the development and installation of online electronic access by the board to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(a)(4) of this chapter.

(5) Requirements for a practitioner providing treatment for a patient at an opioid treatment program operating under IC 12-23-18 to check the INSPECT program:

(A) before initially prescribing a controlled substance to a patient; and

(B) periodically during the course of treatment that uses a

controlled substance.

(b) The board may:

(1) set standards for education courses for individuals authorized to use the INSPECT program;

(2) identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program; and

(3) work with impaired practitioner associations to provide intervention and treatment.

(c) The executive director of the Indiana professional licensing agency may hire a person to serve as the director of the INSPECT program, with the approval of the chairperson of the board.

SECTION 7. IC 35-48-7-17 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 17. (a) The INSPECT oversight committee is established.**

(b) The committee consists of the following members:

(1) The president of the board or the president's designee, who shall serve as the chairperson of the committee.

(2) The commissioner of the state department of health or the commissioner's designee.

(3) The superintendent of the state police department or the superintendent's designee.

(4) The attorney general or the attorney general's designee.

(5) Two (2) lay members who are authorized users of the INSPECT program appointed by the president pro tempore of the senate, not more than one (1) of whom may be affiliated with the same political party.

(6) Two (2) lay members who are authorized users of the INSPECT program appointed by the speaker of the house of representatives, not more than one (1) of whom may be affiliated with the same political party.

(c) The committee shall provide recommendations to the board concerning the implementation of policies, standards, and rules that promote the effective operation of the program.

(d) The committee shall meet:

(1) at least once each calendar year; and

(2) at the call of the chairperson.

(e) Except as provided in subsection (f), the term of a member of the committee appointed under this section is four (4) years. The term of a member of the committee expires July 1, but a member may continue to serve on the committee until a successor is appointed.

(f) The initial terms for the members appointed under this section are as follows:

(1) One (1) member appointed under subsection (b)(5) has a term of four (4) years.

(2) One (1) member appointed under subsection (b)(6) has a term of three (3) years.

(3) One (1) member appointed under subsection (b)(5) has a term of two (2) years.

(4) One (1) member appointed under subsection (b)(6) has a term of one (1) year.

This subsection expires July 1, 2019.

SECTION 8. [EFFECTIVE JULY 1, 2015] **(a) Notwithstanding 410 IAC 17-9-20, for purposes of 410 IAC 17, the term "medication assistance" means the provision of assistance:**

(1) through providing reminders or cues to take medication, the opening of preset medication containers, and providing assistance in the handling or ingesting of medications, including controlled substances, prescription drugs, eye drops, herbs, supplements, and over-the-counter medications; and

(2) to an individual who is unable to accomplish the task due to an impairment and who is:

(A) competent and has directed the services; or

(B) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(b) Before July 1, 2016, the state department of health shall adopt rules under IC 4-22-2 to amend 410 IAC 17-9-20 to adopt the definition of "medical assistance" as set forth in subsection (a).

(c) This SECTION expires on the earlier of the following:

(1) The date that rules are adopted under subsection (b).

(2) January 1, 2017.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 358 as reprinted January 30, 2015.)

CLERE

Committee Vote: yeas 10, nays 0.